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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/431,469	11/01/1999	DAVID M. ARMISTEAD	VPI/95-09-DI	8756

7590

07/17/2002

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EXAMINER

MORAN, MARJORIE A

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 07/17/2002

18

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/431,469

Applicant(s)

ARMISTEAD ET AL.

Examiner

Marjorie A. Moran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 May 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 19-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 25-30 is/are allowed.
- 6) ☒ Claim(s) 19-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                              | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) Paper No(s). <u>17</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                 |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 6) <input type="checkbox"/> Other: _____  |

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. All rejections and objections not repeated below are hereby withdrawn.

***Claim Rejections - 35 USC § 101***

Claims 19-24 are again rejected, as previously set forth in the office action of 12/3/01, under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Applicant's arguments filed 5/7/02 have been fully considered but they are not persuasive. Applicant argues that, as set forth in the State Street and ATT cases, claims reciting algorithms may be statutory if they recite a concrete, tangible and useful result. In support of this argument, applicant points out that, as decided in the Arrhythmia and Alappat cases, consideration of statutory matters must focus on whether a mathematical algorithm is applied in a practical manner to produce a useful result. Applicant further argues that there is no absolute requirement for a transformation of data step. The examiner agrees with all of the above, and wishes to elucidate that she did not intend to suggest that a step of transforming data is necessary, merely that it can be sufficient to render a claim statutory. Likewise, a step of performing a physical act outside the computer is not necessary, but would be sufficient to render a claim statutory. In the instant case, however, the claims do not recite a step of transforming data nor any physical acts performed outside the computer. The claims merely recite a method of mathematical manipulation to "rearrange", but not

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transform data. It is therefore necessary, as admitted by applicant, to determine whether the algorithm (fitting and analysis steps) are applied in a practical manner to achieve a useful result; i.e. do the claims recite a practical application? The result recited in the claims is merely an output of mathematical data (i.e. the "quantified association" of step (b)). Applicant that the quantified association data is a concrete, tangible, and useful result. However, as the data only indicates a quantified result, but does not indicate whether or how the result is to be applied, the result is neither practical not useful. For example, the claim does not recite whether the quantified association actually indicates whether the chemical entity is likely, or not, to bind to, inhibit, etc. a calcineurin. The result of the claims is merely an invitation to do further research. By comparison, the share price which is the result in the ATT case is both practical and useful; no further calculations or research are necessary in order to make use of the result. Similarly, the signal output in the ATT is both practical and useful; again, no further calculations or method steps are required to determine what to do with the signal. In the instant claims, further steps and/or calculations are required before one performing the method would be able to use the result. The result of the claimed method, therefore, is merely an invitation to do further research, and is not, in itself, a concrete, tangible, and useful result.

For these reasons, the rejection is maintained.

***Claim Rejections - 35 USC § 103***

Claims 19-24 are again rejected, as previously set forth in the office action of 12/3/01 under 35 U.S.C. 103(a) as being unpatentable over HENDRY (US 5,705,335, filed 11/26/1993).

Applicant argues that the computational means and structural coordinates recited in the claims are required for the functionality of the instantly claimed methods, and therefore must be given patentable weight. In response, applicant is directed to the definition of functional descriptive material set forth in MPEP 2106:

Descriptive material can be characterized as either "functional descriptive material" or "nonfunctional descriptive material." In this context, "functional descriptive material" consists of data structures and computer programs which impart functionality when employed as a computer component. (The definition of "data structure" is "a physical or logical relationship among data elements, designed to support specific data manipulation functions." The New IEEE Standard Dictionary of Electrical and Electronics Terms 308 (5th ed. 1993).) "Nonfunctional descriptive material" includes but is not limited to music, literary works and a compilation or mere arrangement of data.

The structure coordinates recited in the instant claims are merely datasets, and are neither a data structure nor a program. As the "computational means" of the instant claims is merely a means for "comparing" the datasets, but does functionally interact with the data (i.e. the "fitting" step does not require that the data be changed in any way), then neither the computational means nor the structural data IS required for functionality, and the structural data is not given patentable weight.

As the structure coordinates recited in the claims are not given patentable weight, they do not distinguish the claimed method from the prior art in terms of patentability, and the rejection is maintained.

### ***Allowable Subject Matter***

The following is a statement of reasons for the indication of allowable subject matter in claims 25-30: The closest prior art of CHENG et al. (Biochem. (1994) vol. 33 (14), pp. 4093-4100) teaches NMR studies of an FKBP-12/FK506 complex in order to characterize binding of these compounds to calcineurin (CN), but also teaches that the crystal structure of CN or a ternary complex comprising CN were not known at the time of publication (p. 4094). The prior art does not teach or fairly suggest a three dimensional structure of a molecule comprising a CnA-like binding pocket with the coordinates recited in the claims, therefore using the structure to design, select and test a compound for binding to the structure is neither taught nor fairly suggested. .

### ***Conclusion***

Claims 19-24 are again rejected; claims 25-30 are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

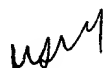
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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

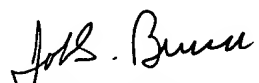
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (703) 305-2363. The examiner can normally be reached on Monday to Friday, 7:30 am to 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (703) 308-4028. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to a patent analyst, Tina Plunkett, whose telephone number is (703) 305-3524.

  
Marjorie A. Moran  
Examiner  
Art Unit 1631

July 12, 2002

  
JOHN S. BRUSCA, PH.D  
PRIMARY EXAMINER